REMARKS

The present invention relates in part to methods for determining the ratio of the amount of oxidized troponin I in a solution to the amount of reduced troponin I in the solution. These methods utilize a first component (*e.g.*, an antibody or a receptor) having a specific binding affinity for each of oxidized and reduced troponin I, and a second component (*e.g.*, a different antibody or receptor) that has a specific binding affinity that provides binding to only the one of oxidized and reduced troponin I bound to the first component. By measuring a signal from the complex containing both the first component and the second component, the ratio of oxidized to reduced troponin I may be determined without the need to determine the actual concentrations of either troponin I form.

Prior to the present submission, claims 1-17 were pending in the application. Claims 11-16 are cancelled herein. Applicant expressly reserves the right to prosecute subject matter no longer or not yet claimed in one or more applications that may claim priority to the present application.

Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Non-Art Based Remarks

1. 35 U.S.C. § 112, first paragraph (written description)

Applicant disagrees that claims 14-16 do not satisfy the written description requirement. In an effort to advance prosecution however, claims 14-16 are cancelled herein, rendering the rejection under 35 U.S.C. §112, first paragraph moot.

2. 35 U.S.C. § 112, second paragraph (definiteness)

Applicant respectfully traverse the rejection of claim 9 under 35 U.S.C. §112, second paragraph as allegedly being indefinite because "it is not clear what is the normalizing factor."

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). Recognizing that the

English language is not always precise, the settled law has established that the essential inquiry in a definiteness analysis is whether the claims set out and circumscribe the claimed subject matter with reasonable particularity. *See, e.g.*, MPEP § 2173.02; *see also, Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) ("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.") (emphasis added). Definiteness is not analyzed in a vacuum, but in light of the content of the specification, and with the knowledge available to the skilled artisan.

The present specification informs the reader in paragraph [0067] as follows: a binding moiety having specific binding affinity for each of the biological molecules of interest (which, in the present claims is the first antibody that binds reduced and oxidized cardiac troponin I) may bind to the biological molecules of interest with equal affinity or with unequal affinity. If the biological molecules bind with unequal affinity, a normalizing factor can be determined to correct for the actual ratio of the biological molecules bound to the first component. Thus, the normalizing factor is a multiplication factor correcting for the relative bias of an antibody binding A vs. B. Indeed, the specification provides Example 6, which describes how to determine and use such a normalizing factor in precisely these terms.

Applicant respectfully submits that, when claim 9 is properly read in the light of the specification, the skilled artisan is reasonably apprised of the scope of the invention. Because 35 U.S.C. §112, second paragraph demands no more, Applicant requests that the rejection be reconsidered and withdrawn.

Art Based Remarks

3. Obviousness-type double patenting

Applicant respectfully submits that the terminal disclaimer submitted herewith renders moot the rejection based on U.S. Patent 6,670,196.

4. Rejections under 35 U.S.C. §§ 102 and 103

Applicant respectfully traverses the rejection of claims 1-5, 7, 10-13, and 17 under 35 U.S.C. §102(b), as allegedly being anticipated by Buechler *et al.*, WO96/33415, and the rejection of claims 8 and 9 under 35 U.S.C. §103(a), as allegedly being unpatentable over WO96/33415 in view of Vanderlaan *et al.*, U.S. Patent 5,429,925.

Applicant respectfully disagrees that WO96/33415, alone or in combination with Vanderlaan *et al.*, discloses or suggests the invention as presently claimed.

Notwithstanding this, Applicant submits that WO96/33415 was not published more than one year prior to the priority date of the present application, and thus is not prior art under 35 U.S.C. §102(b) to the present application, as the Examiner asserts in the rejection. The present application claims priority to provisional U.S. Patent Applications 60/046,467 and 60/047,081, filed on May 14, 1997 and May 19, 1997, respectively. WO96/33415 was published on October 24, 1996.

Insofar as the Examiner considers WO96/33415 to be prior art under 35 U.S.C. §102(a), Applicant notes that Kenneth F. Buechler, listed as sole inventor of the present application, is also listed as one of two inventors on WO96/33415. Provided herewith is a declaration by Dr. Buechler, submitted in accordance with 37 C.F.R. §1.132, in which he states that, to the extent the presently claimed invention is disclosed in WO96/33415, he alone conceived that invention. Thus, Applicant submits that WO96/33415 is also not prior art under 35 U.S.C. §102(a).

Because the WO96/33415, alone or in combination with Vanderlaan *et al.*, fails to disclose or suggest the invention as presently claimed, and because WO96/33415 is not available as prior art to the present application, Applicant respectfully requests that the rejections under 35 U.S.C. §§ 102 and 103 be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,

Date 02/15/2006

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